Section II

NOV 3 0 2004

K040744

Summary of Safety and Effectiveness
(as required by 21 CFR 807.92)

Atrilaze™ Soft Tissue Ablation System

Submitter: MedicalCV, Inc.
9725 South Robert Trail
Inver Grove Heights, MN 55077
USA

Contact: Denny Steger
V.P. RA/QA
Phone: 651 452 3000
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Date of Summary: November 18, 2004

Classification Name: Laser Instrument, Surgical Powered

Common Name: Surgical Laser Instrument

Proprietary Atrilaze™ Soft Tissue Ablation System

Description of Device: The Altrilaze Soft Tissue Ablation System consists of a generator designed for the delivery of 810nm laser light and a hand held fiber optic light delivery device (probe) fitted with a standard SMA 905 connector at the proximal end. The system may be used in conjunction with surgical treatment for hemostasis, incision, ablation, coagulation and vaporization of tissue as required by the clinician.

Statement of Intended Use: The MedicalCV Atrilaze Soft Tissue Ablation System is indicated for the delivery of 810nm laser light to soft tissue to include cardiac tissue, during surgical procedures. Indications include the incision, excision, dissection, vaporization, ablation or coagulation of soft tissue.

Warning: The Atrilaze Ablation System is not indicated for the treatment of cardiac arrhythmias.

The risk of actual damage to adjacent organs from the instrument exists and perforation, rupture or tearing of tissue, may occur as a complication of laser use. Burns can occur if the laser energy is not correctly applied. These complications may be serious.

Technological Comparison: The Atrilaze Soft Tissue Ablation System is a self contained compact surgical laser that utilizes gallium aluminum arsenide (GaAlAs) semiconductor diodes to generate near-infrared laser radiation. A fiber optic delivery system (probe) is coupled to the laser via an SMA 905 connector to deliver laser radiation to the target tissue(s). For purposes of this submission, the Atrilaze Soft Tissue Ablation System was compared to the following predicate device(s):

- Biolitec/Ceramoptec Ceralas D10-25 Fiber-coupled Diode Laser System (K001975)
- CardioFocus Diode Laser System (K013201)

Testing: The results of biocompatibility testing support that the materials used in the manufacture of the Altrilaze Soft Tissue Ablation disposable probe are non-toxic, non-hemolytic, and non-pyrogenic. All biocompatibility testing was conducted under Good Laboratory Practices per 21 CFR Part 58. Performance testing for the Atrilaze Soft Tissue Ablation System included compliance to manufacturing specifications for Power Output, Tip Pull-Off, Pressure and Flow for the fiber optic delivery device, also visual evaluation of the lesions obtained using the Altrilaze Soft Tissue Ablation System on cardiac tissue was performed. Testing demonstrated that the Altrilaze Soft Tissue Ablation System is substantially equivalent to the predicate devices for ablation of soft tissue.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 21 2008

MedicalCV, Inc
c/o Mr. Denny Steger
Vice President Regulatory Affairs/Quality Assurance
9725 South Robert Trail
Inver Grove Heights, MN 55077

Re: K040744
Trade/Device Name: Atrilaze™ Soft Tissue Ablation System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II (two)
Product Code: OCL, GEX
Dated: August 31, 2004
Received: September 1, 2004

Dear Mr. Steger:

This letter corrects our substantially equivalent letter of November 30, 2004.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(K) Number: K040744

Device Name: Atrilaze™ Ablation System

Indications for Use: The MedicalCV, Inc. Atrilaze™ Soft Tissue Ablation System is indicated for delivery of 810nm laser light to soft tissue to include cardiac tissue during surgical procedures. Indications include the incision, excision, dissection, vaporization, ablation, or coagulation of soft tissue.

Warning: The Atrilaze™ Ablation System is not indicated for the treatment of cardiac arrhythmias.

The risk of actual damage to adjacent organs from the instrument exists and perforation, rupture or tearing of tissue, may occur as a complication of laser use. Burns can occur if the laser energy is not correctly applied. These complications may be serious.

Prescription Use__X__ OR Over–the-Counter Use____
(Per 21 CFR 801.109)

(Please do not write below this line – Continue on another page if necessary)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K040744